

Kingdom of Saudi Arabia المملكة العربية السعودية Ministry of Health وزارة الصحة Jazan Hospital IRB



15 April 2020

TO : Dr Ehab S Alameer

FROM : Head of Jazan Hospital IRB (H-10-Z-068)

RE : Research Proposal Submitted for Review

I am pleased to inform you that your submitted research proposal entitled 'Outcomes of surgery in COVID-19 infection (CovidSurg)' (NO. 2018) has been reviewed and approved by the committee. This ethical approval is valid for 6 months from the date of approval.

We wish you success with your work.

Sincerely,

Dr. Yahia Solan, MBBS, MD

Head of the Jazan Hospital IRB Ministry of Health, Saudi Arabia an Hospital

Email: JazanIRB@moh.gov.sa Tel: +966 173342981





RESEARCH ETHICS COMMITTEE

MBC: , Ext: 32939 , Fax: Click to edit

INTERNAL MEMO

TO: Amal Alhefdhi

Consultant, Breast And Endocrine Surgery

Surgery Department - Riyadh

FROM: Rana Moslmani

CoChairman

Research Ethics Committee

DATE: 28 Shaban 1441

21 April 2020

REF: C380/765/41

SUBJECT: NEW PROPOSAL - RAC # 2201065: OUTCOMES OF SURGERY IN COVID-19
INFECTION: INTERNATIONAL COHORT STUDY (COVIDSURG)

The above - referenced proposal was reviewed by the Research Ethics Committee on 19 April 2020 through Expedited Review process.

It is my pleasure to inform you that the Committee has recommended the proposal and the Waiver of Signed Consent for approval; and I would like to take this opportunity to congratulate you on behalf of the Research Advisory Council (RAC).

Please be informed that in conducting this study, the Investigators are required to abide by the rules and regulations of the Government of Saudi Arabia, KFSH&RC, and the Research Advisory Council. Further, you are required to submit a Progress Report by 19 March 2021 so that it can be reviewed by reviewing Committee(s) without lapse of approval. The approval of this proposal will automatically be suspended on 19 April 2021 pending the acceptance of the report. You also need to notify the Office of Research Affairs s soon as possible in the case of any amendments to the project, termination of the study or any new information that may affect the benefit/risk ratio of the proposal.

Please observe the following:

- 1. Personally identifying data should only be collected when necessary for research;
- 2. The data collected should only be used for this proposal;
- 3. Data should be stored securely so that only a few authorized users are permitted access to the database;
- 4. Secondary disclosures of personally identifiable data are not allowed;
- 5. The process of obtaining the verbal consents should be documented in the Medical Records of enrolled subjects. This should clearly specify:
- The research subjects' acceptance to participate in the study;
- The project's RAC number;

Page 2 / 2, Reference: C380/765/41

- The date the verbal consent was obtained;
- The name and signature of the Principal Investigator/ delegate.

Please note that the Collaborative Research Agreement with the main collaborating centre is not signed. Please make sure that the agreement is singed before data sharing starts. You may contact the Sponsored Research Section (aomer@kfshrc.edu.sa) for assistance.

We wish you every success in your research endeavors.

RWM/ahs

CC: Mohammad Bazarbashi, MD, Chairman, C380

Hunida Mohamed, Clinical Research Coordinator, SURG